UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF ILLINOIS, STATE OF MARYLAND, STATE OF WASHINGTON, Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	:	07 Civ. 8621 (PAC) ECF CASE

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANT'S MOTION TO DISMISS AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

MICHAEL J. GARCIA
United States Attorney for the
Southern District of New York
Attorney for Defendant

SERRIN TURNER
Assistant United States Attorney
86 Chambers Street
New York, New York 10007
Telephone: (212) 637-2701
Facsimile: (212) 637-2686
serrin.turner@usdoj.gov

TABLE OF CONTENTS

PRELIMINARY STATEMENT

This case has been brought at the wrong time, in the wrong court. Plaintiffs seek to challenge a policy statement that has no binding force by itself, and whose precise effect on them will not be known until such time as it is actually applied to their respective state plans in final, individualized administrative decisions. Any such decision, once rendered, would be subject to immediate judicial review in circuit court pursuant to the SCHIP statute. Plaintiffs have no need – and no right – to obtain review in this Court now.

Fundamentally, the case is unripe. Further administrative process is required before any final agency action could be taken with respect to plaintiffs' state plans. The potential remains that, through that process, the differences between the parties would be narrowed. Indeed, follow-up guidance that CMS has already provided to the states has proven many of the plaintiffs' concerns about the SHO Letter to be unfounded. Even the plaintiffs' procedural challenge would benefit from awaiting further administrative developments, because it rests largely on a prediction about how CMS will treat the SHO Letter in compliance proceedings that have yet to occur. Thus, judicial review should be withheld for the time being, until the administrative process has played itself out and any remaining disputes between the parties have taken final shape.

In the meantime, plaintiffs cannot claim to be suffering hardship, because the SHO Letter does not have any present binding effect. At this point, CMS is merely seeking to work cooperatively with states in revising their plans in light of the letter's guidance. Although the SHO Letter advises that CMS may later seek to compel states to comply with the letter's terms if their cooperation is not forthcoming, the law is clear that such notice by itself does not impose legal obligations or give rise to any cognizable harm. The SHO Letter expressly states that CMS does not intend to undertake compliance proceedings until August 2008 at the earliest; and, if and when such proceedings are eventually brought against any state, the state would be entitled to

defend its position in a full hearing on the record before any sanction could be imposed. Such sanction would be prospective only and would not apply to the state's present conduct.

Even if any plaintiff did have a ripe case, it would not belong in this Court. It would belong in circuit court under 42 U.S.C. § 1316(a) – the Medicaid judicial review provision incorporated into by reference into the SCHIP statute. Plaintiffs' attempt to portray their claims as "collateral" to the types of claims covered by this provision is unavailing. Courts of appeal reviewing cases brought under § 1316(a) can and do consider challenges, both substantive and procedural, to the validity of federal requirements. Contrary to plaintiffs' contentions, circuit court jurisdiction under the statute is not limited to cases merely challenging the application of those requirements to a particular state plan. Because plaintiffs could thus obtain review under the statutory scheme designated by Congress, they are not entitled to follow a different route of their own choosing.

Finally, in the event that the Court did reach plaintiffs' claim that the SHO Letter is a legislative rule subject to rulemaking requirements, the claim should be rejected. It fails for the same reason that plaintiffs' ripeness arguments fail: unlike a legislative rule, the SHO Letter has no legally binding effect by itself, for the letter can only be given such effect through further administrative process. In particular, the SHO Letter does not legally bind *the agency* – as a legislative rule would – for CMS retains discretion to decide whether and how to apply the review strategy described in the letter on a case-by-case basis. Moreover, the SHO Letter is not a legislative rule simply because it supplies specific guidance about how the agency intends to apply ambiguous and discretionary standards embodied in existing statutory and regulatory requirements. That is precisely the function of a general statement of policy or interpretive rule.

POINT I

THE COURT LACKS JURISDICTION OVER THE COMPLAINT

A. Plaintiffs' Claims Are Not Ripe

1. The SHO Letter Does Not Constitute Final Agency Action

This case is unripe first and foremost because the SHO Letter does not constitute final agency action. For an agency action to be "final," it must "mark the consummation of the agency's decisionmaking process" and be an action "by which rights or obligations have been determined or from which legal consequences will flow." *Air Espana v. Brien*, 165 F.3d 148, 152-53 (2d Cir. 1999) (internal quotation marks omitted). Neither is true of the SHO Letter.[1]

a. The SHO Letter Does Not Consummate the Agency's Decisionmaking

Rather than marking the consummation of any decisionmaking process, the SHO Letter merely forecasts how CMS intends to approach decisionmaking in future administrative proceedings. That is where any final decisions relating to plaintiffs' state plans would ultimately unfold. How the agency will treat the SHO Letter in practice can only be determined by awaiting the outcome of those future proceedings – in which states have ample opportunity to press their own views, through both informal negotiations and the formal hearing process.

Already, even before such proceedings have commenced, CMS has fielded numerous inquiries from various states concerning the SHO Letter, and the follow-up guidance it has provided demonstrates that plaintiffs' concerns may well be allayed in any final decisions CMS makes regarding their state plans. For example, contrary to plaintiffs' claim in their brief that CMS "will allow no exceptions for undue hardship" to the 12-month uninsurance period speci-

[1] The finality requirement is a jurisdictional prerequisite under the APA, *see Air Espana*, 165 F.3d at 152, and hence the Court need not address any other ripeness factor to dismiss the case.

fied in the SHO Letter, Pls.' Br.[2] at 42, plaintiffs' own declarations reveal that CMS has represented to the State of Washington that it will consider such exceptions on a case-by-case basis. *See* Declaration of Kevin Cornell ("Cornell Decl."), Ex. 3, at 2 (email from CMS SCHIP Director to Washington SCHIP representative) ("In terms of exceptions to the period of uninsurance, we will review any proposed exceptions and justifications in making a determination [on the state's plan]."). Likewise, CMS has made plain that it will afford states considerable flexibility in establishing that they have enrolled 95 percent of children below 250% FPL, in light of well known shortcomings in census data. *See id.* ¶ 5 (stating that, during teleconference, "CMS representatives demonstrated a willingness to be flexible about the source of data Washington could rely upon to establish the August 17 requirements"); *id.* Ex. 3, at 1 (email discussing flexibility regarding data sources). Notwithstanding plaintiffs' insistence in their complaint that the 95-percent enrollment target will bar states as a practical matter from extending coverage above 250% FPL, *see* Compl. ¶ 44, a CMS official recently elaborated during congressional testimony that CMS believes that accurate data "would demonstrate that a number of states are already meeting the 95 percent goal." *Covering Uninsured Children: The Impact of the August 17 SCHIP Directive, Before the S. Comm. on Finance* (April 9, 2008) (statement of Dennis G. Smith, Director, Center for Medicaid and State Operations, CMS) ("Smith Testimony"), *available at* http://www.senate.gov/~finance/hearings/testimony/2008test/040908dstest.pdf.

Even more recently, CMS sent a letter to all state health officials about various recurring issues that have arisen in the agency's ongoing discussions with the states. *See* Second Declaration of Serrin Turner ("Second Turner Decl."), Ex. A. This guidance, too, significantly narrows

[2] This brief uses "Def.'s Br." to refer to the defendant's memorandum in support of its motion to dismiss, and "Pls.' Br." to refer to the state plaintiffs' memorandum in opposition.

the divide between CMS and the plaintiffs. In particular, contrary to plaintiffs' apprehension that the SHO Letter will "apply to *current*, in addition to new, enrollees," Pls.' Br. at 21 (emphasis in original), the follow-up letter reaffirms what was already stated fairly clearly in the SHO Letter itself – that any changes made to a state's plan in response to the SHO Letter need only be applied prospectively and that all current enrollees "can be grandfathered into the State's current coverage and cost-sharing levels." *Id.* at 1. The follow-up letter also further signals that CMS intends to take a flexible approach in applying the review strategy outlined in the SHO Letter. It states that CMS will consider not only exceptions but also *alternatives* to the 12-month uninsurance period specified in the SHO Letter. *Id.* at 2. In the same vein, it emphasizes that the 95-percent core-population enrollment target is "an achievable goal" and that CMS will "work individually with affected States on different approaches to document this assurance." *Id.* More generally, the letter makes explicit that CMS retains the prerogative to make exceptions to the policies outlined in the SHO Letter if a state's individual circumstances so warrant:

> The purpose of the crowd-out procedures and assurances discussed in the August 17th letter is to ensure compliance with existing regulatory requirements by reasonably protecting against crowd-out and otherwise ensuring the effective and efficient operation of the SCHIP program in serving the most vulnerable low income populations, when coverage is extended to populations with higher income levels. *Because State programs . . . vary widely, we will continue to work with affected States and review requests for alternative approaches on a case-by-case basis* to ensure compliance with these existing requirements of law.

Id. (emphasis added).

Not only has CMS preserved such flexibility in word; it has demonstrated it in action, in the course of reviewing material submitted by the State of Rhode Island. Rhode Island currently provides coverage above 250% FPL and was recently seeking to demonstrate compliance with federal requirements without including a 12-month uninsurance period as part of its crowd-out procedures. As an alternative, the state proposed relying on mandated enrollment in its premium

assistance program for any Medicaid- or SCHIP-eligible individuals in the state with access to employer-sponsored insurance. By letter dated May 9, 2008, CMS advised Rhode Island that "this is an acceptable alternative to the one-year period of uninsurance," given that mandatory enrollment in a premium assistance program "eliminates the need for a waiting period." *See* Second Turner Decl., Ex. B, at 2. Further, the letter also advised that Rhode Island had offered adequate assurance that 95 percent of children in the state below 250% FPL had health insurance – a showing that Rhode Island made by adjusting its population data to exclude categories of children ineligible for SCHIP or Medicaid coverage. *Id.* at 1.

These developments make it abundantly clear that the SHO Letter marks the start, not the endpoint, of agency negotiation and decisionmaking concerning how states can provide coverage above 250% FPL consistently with existing program requirements. As a result, it cannot be predicted with any certainty what exactly CMS will ultimately require of the plaintiffs here as a condition to providing such coverage. The areas of potential disagreement between plaintiffs and CMS have already been significantly bridged by agency guidance to date, and, given CMS's indications that it intends to apply the SHO Letter in a flexible fashion, the potential remains that those differences will be bridged further through subsequent administrative process. Accordingly, the SHO Letter itself does not mark the final step in the agency's relevant decision-making process and thus does not constitute "final agency action," making judicial review premature. *See, e.g.*, *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 736 (1998) ("[D]epending upon the agency's future actions to revise the Plan or modify the expected methods of implementation, review now may turn out to have been unnecessary.").

b. The SHO Letter Does Not Have Any Legally Binding Effect

The second reason that the SHO Letter does not constitute final agency action is that it is not an action "by which rights or obligations have been determined or from which legal conse-

quences will flow." Plaintiffs' argument that "immediate compliance" with the letter is "expected" by the agency, Pls.' Br. at 22-23, conflates the concept of voluntary compliance – which the letter does seek from affected states – with a *legal obligation* to comply – which can only be imposed through further administrative process.

As explained in defendant's initial brief, the only way that CMS can make a legally binding determination that a state's plan is out of compliance with federal requirements is through a compliance proceeding, in which the state has the opportunity for a full hearing on the record before any final agency decision is rendered. Only after such a determination has been made can CMS put the state to the choice of complying with the agency's determination or giving up program funding (in whole or, more likely, in part). *See* Def.'s Br. at 9-10.

Thus, the only "threat" presently facing states affected by the SHO Letter is the risk of *future* compliance proceedings.[3] Unless and until CMS makes a final non-compliance determination against a state at the end of such a proceeding, the state will not face the choice of complying with the SHO Letter's guidance or giving up program funding. The SHO Letter itself makes clear that such compliance actions will not even be initiated until August 2008, at the earliest. For now, the agency has simply notified affected states of the possibility of such compliance proceedings and, in the interim, has sought their cooperation in amending their plans in order to make future compliance proceedings unnecessary.

The D.C. Circuit addressed an analogous situation in *Reliable Automatic Sprinkler Company v. CPSC*, 324 F.3d 726 (D.C. Cir. 2003). There, the Consumer Product Safety Commission

[3] Among plaintiffs here, only Washington and Maryland can claim to face even this hypothetical threat. Because New York and Illinois do not extend coverage above 250% FPL under their current plans, the SHO Letter does not subject them to any threat of compliance action at all. (New York's ongoing plan amendment proceedings are another matter. *See infra* at 14-18.)

sent a letter to a manufacturer of automatic sprinkler heads advising that the agency intended to initiate compliance proceedings against the company based on a preliminary determination that its products were hazardous. *Id.* at 729-30. The letter was sent to give the company a chance to avoid the contemplated proceedings by taking corrective action voluntarily. *Id.* The company brought suit, arguing that the letter reflected an erroneous final determination by the agency that it had jurisdiction over the products in question, which the company contested. *Id.* The D.C. Circuit rejected this argument, finding that the letter did not constitute final agency action within the meaning of the APA. It explained:

> The Act and the agency's regulations clearly prescribe a scheme whereby the agency must hold a formal, on-the-record adjudication before it can make any determination that is legally binding. Here, the agency has not yet taken the steps required under the statutory and regulatory scheme for its actions to have any legal consequences. In the event that the agency should decide to pursue enforcement action against Reliable, the agency must, in the course of the formal adjudication, afford Reliable the opportunity to convince the agency that the term "consumer product" does not include Reliable's sprinkler heads and that the agency therefore lacks jurisdiction to regulate them. But to date, the agency has not even filed an administrative complaint against Reliable. * * * No legal consequences flow from the agency's conduct to date, for there has been no order compelling Reliable to do anything. *To be sure, there may be practical consequences, namely the choice Reliable faces between voluntary compliance with the agency's request for corrective action and the prospect of having to defend itself in an administrative hearing should the agency actually decide to pursue enforcement. But the request for voluntary compliance clearly has no legally binding effect.*

Id. at 732 (paragraph structure altered) (emphasis added); *see also DRG Funding Corp. v. HUD*, 76 F.3d 1212, 1214 (D.C. Cir. 1996) (agency action is not final if it "'does not itself adversely affect complainant but only affects his rights adversely on the contingency of future administrative action'") (quoting *Rochester Tel. Corp. v. United States*, 307 U.S. 125, 130 (1939)).

Similarly, here, under the SCHIP statute and implementing regulations, CMS cannot impose sanctions for plan non-compliance until after a compliance hearing. 42 U.S.C. §§ 1397ff(c),(d); 42 C.F.R. §§ 457.203, 457.204. The SHO Letter itself does not give rise to

such legal consequences. While it may have the practical effect of leading states to comply in order to avoid future compliance action, such practical effects are not sufficient to qualify the letter as a final agency action. *See Ctr. for Auto Safety v. NHTSA*, 452 F.3d 798, 811 (D.C. Cir. 2006) ("The flaw in appellants' argument is that the "consequences" to which they allude are practical, not legal. . . . *[D]e facto* compliance is not enough to establish that the guidelines have had *legal* consequences.") (emphasis in original); *cf. Top Choice Distributors*, 138 F.3d at 467 ("[T]he administrative complaint has no effect except to force plaintiffs to respond, an effect that does not amount to a cognizable legal consequence."); *In re Combustion Equip. Assocs.*, 838 F.2d 35, 38 (2d Cir. 1988) ("The PRP letter is not a final, definitive ruling with the status of a law demanding immediate compliance since it does not impose any liability . . . .").

In this respect, the instant case is readily distinguishable from *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), on which plaintiffs rely, Pls.' Br. at 23. In that case, drug manufacturers challenged newly promulgated regulations governing the labeling of their products. *Abbott Labs.*, 387 U.S. at 138. The regulations at issue were "self-operative," *id.* at 148, "made effective immediately upon publication," *id.* at 153, and had "the status of law," *id.* at 152. Drug manufacturers were thus directly required to comply with the regulations on pain of "heavy criminal and civil sanctions." *Id.* at 152. On these facts, the Court held that the manufacturers were not required to await actual prosecution in order to challenge the regulations; it was enough that they were *presently* subject to penalties for their conduct. *Id.* at 153 (holding that review is available where challenged regulation "requires an *immediate* and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance") (emphasis added).

In contrast to the regulations in *Abbott Laboratories*, the SHO Letter is not "self-operative," is not "effective immediately," and does not have the "status of law." The only way that CMS can make a legally binding determination that a plan is in non-compliance with federal requirements based on the policies reflected in the SHO Letter is through a compliance proceeding. In the event of such a determination, the state would then – going forward – face a choice between changing its plan in response to the agency's determination or else giving up program funds. But, unlike the drug manufacturers in *Abbott Laboratories*, states here are under no threat of sanction for their *present* conduct. They have merely been given advance notice of *future* legal obligations the agency may impose. That is not enough. Final agency action imposes legal obligations effective *now*. *See FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 242 (1980) (holding that initiation of compliance proceedings was not final agency action given that cease and desist order could only be issued at the end of the compliance process, and contrasting case with *Abbott Laboratories*, in which regulations "forced manufacturers to 'risk serious criminal and civil penalties' for non-compliance").

Nor does it matter that plaintiffs seek to bring a "facial" challenge to CMS's authority to implement the policies in the SHO Letter, prior to the actual application of those policies to plaintiffs' state plans. The point remains that these policies cannot be given binding legal effect without further administrative process. The D.C. Circuit similarly found it irrelevant in *Reliable* that the plaintiff there sought to bring a pre-enforcement challenge to the agency's interpretation of "consumer product," on which the agency's authority to take enforcement action against the company depended. As the Court explained: "Certainly the agency's investigation *assumes* for now that it has jurisdiction to regulate the sprinkler heads. But the agency has not yet made any determination or issued any order imposing any obligation on Reliable, denying any right of Re-

liable, or fixing any legal relationship." 324 F.3d at 731-32 (emphasis in original). Likewise, while the SHO Letter reflects an assumption that existing statutory and regulatory provisions give CMS adequate authority to take enforcement action in accordance with the letter, plaintiffs must wait until such enforcement action is actually taken and finalized before they may seek to test this assumption in court. *See AT&T v. EEOC*, 270 F.3d 973, 975 (D.C. Cir. 2001) (agency action not final "when an agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party").

2. Plaintiffs' Claims Would Benefit from Further Factual Development

Beyond the lack of final agency action, another reason the case is unripe is that plaintiffs' claims turn on issues that would benefit from further factual development at the administrative level. This is true not only for plaintiffs' substantive challenge, but for their procedural challenge as well.

As set forth in defendant's initial brief, plaintiffs' claim that the review strategy in the SHO Letter is arbitrary, capricious, and contrary to law turns ultimately on factual issues, concerning whether the various elements of that strategy are necessary to prevent crowd-out and otherwise to provide coverage to low-income children in an efficient and effective manner. *See* Def.'s Br. at 18-21. Plaintiffs do not contend otherwise, as they acknowledge that "there may be some factual debate" with respect to these issues. Pls.' Br. at 25. Instead, they contend that the necessary facts may be developed through discovery and trial in district court. *Id.*

Yet plaintiffs' argument ignores that judicial review of the reasonableness of agency action is presumptively based on the "administrative record already in existence, not some new record made initially in the reviewing court." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) (internal quotation marks omitted). There is no reason why plaintiffs should be allowed to build a record in court that they would have the opportunity to build before the agency

in the course of appropriate administrative proceedings. (Indeed, plaintiff New York is building just such a record this moment during the discovery period afforded as part of CMS's plan-amendment hearing process.) Rather, judicial review of the SHO Letter's substance must await the conclusion of an adjudicative proceeding where the review strategy in the letter is actually applied and a corresponding administrative record is developed on which review could be based. *Cf. Fla. Power & Light*, 470 U.S. at 744 ("[I]f the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course . . . is to remand to the agency for additional investigation or explanation."); *cf. also N.Y. Dep't of Social Services v. Shalala*, 21 F.3d 485, 494 (barring state from raising factual dispute in court that it could have raised administratively, for to do otherwise "would encourage others not to litigate legal and factual issues in the first instance before the [agency]").

Even plaintiffs' procedural claim – *i.e.*, their claim that the SHO Letter constitutes a legislative rule that was required to be promulgated through rulemaking – could benefit from further factual development, of a kind. Much of plaintiffs' argument on this claim aims at showing that the agency intends to treat the SHO Letter as a "legally binding norm" that "limits the agency's own discretion." Pls.' Br. at 34. Yet, insofar as plaintiffs' argument amounts to a prediction about how the agency will treat the SHO Letter in making plan-conformity determinations, then the proper course is to wait until such determinations are actually made and the agency's reasoning is formalized in final, binding decisions.

The D.C. Circuit's decision in *Public Citizen v. U.S. Nuclear Regulatory Commission*, 940 F.2d 679 (D.C. Cir. 1991), provides a useful comparison. At issue there was a statement put out by the Nuclear Regulatory Commission specifying detailed criteria that the agency intended to use in deciding whether to exempt radioactive materials from regulation. *Id.* at 680. Pre-

viously, the agency had made such exemptions *ad hoc*, based on whether regulation of the materials would yield a "net societal benefit." *Id.* at 680-81. Plaintiffs claimed that the statement was a legislative rule requiring notice-and-comment procedures, pointing to "unequivocal language" used in the statement's text. *Id.* at 682. For example, the statement purported to "*establish[]* a baseline level of risk" beyond which the agency would not regulate. *Id.* (emphasis in original). Moreover, "in a break with prior [agency] policy," the statement asserted that the agency "*will not consider* whether a practice is justified in terms of net societal benefit." *Id.* (emphasis in original).

The Court declined to find this language decisive, however, given that the text of the statement also contained "indications cutting the other way." *Id.* Most significantly, "the policy statement [made] it clear that the decisions [about particular exemptions] have not yet been taken," as the statement described its purpose to be the establishment of a "risk framework" for making such decisions in the future, *id.* – much as the SHO Letter describes the agency's "review strategy" for making decisions in future adjudications of state plan material. Also, the statement noted that the agency retained discretion to make exceptions to the criteria in special circumstances, *id.* – just as CMS retains discretion to make exceptions to the policies in the SHO Letter, as CMS's recent follow-up guidance to the states explicitly affirms. Accordingly, the D.C. Circuit concluded that it was unwise to adjudicate plaintiffs' rulemaking challenge in advance of the statement's actual application in specific administrative proceedings – which was the only way to tell for sure whether the agency intended to treat the statement as a binding rule that constrained its own discretion. *Id.* at 683 ("The statement's own signals being in conflict, only Commission practice under the policy can make the issue determinable and thus fit for review."); *see also Hudson v. FAA*, 192 F.3d 1031, 1034-35 (D.C. Cir. 1999) ("[W]e have often

held that an early procedural challenge to a purported policy statement [on the ground that it is actually a legislative rule] is not ripe because it is not yet demonstrable that the agency intends to treat it as having the characteristics of a rule.").

The same forbearance is appropriate here. While plaintiffs allege that CMS will brook no challenge to the SHO Letter in administrative proceedings and will consider itself to lack any discretion to deviate from its terms, the only way to test these predictions definitively is to await the actual conclusion of such proceedings. And no administrative proceedings involving the SHO Letter have been concluded to date.

The various preliminary and informal communications on which plaintiffs attempt to rely instead are no substitute for such final decisions. Plaintiffs err particularly in the reliance they place on a CMS letter sent to New York in anticipation of the state's upcoming plan-amendment hearing. Contrary to plaintiffs' allegations that the letter "suggest[s] an intention to disregard any challenges to the policies contained in the [SHO] letter," Pls.' Br. at 24, this is purely plaintiffs' own gloss; the letter evidences no such intention. It simply frames the issues for the hearing in terms of whether New York's proposed plan amendment conforms to relevant statutory and regulatory requirements.[4] This is entirely unremarkable, since the fundamental issue at any

---

[4] The letter states that the following will be at issue at the hearing:

- Whether the State has demonstrated that SPA #10 [*i.e.*, the state plan amendment] is consistent with the requirement in section 2101(a) of the Act for effective and efficient program operation. . . . ;
- Whether New York has demonstrated that SPA #10 is consistent with the requirements in section 2102(a) to identify and enroll all uncovered children who are eligible to participate in public health insurance programs, to ensure that the SCHIP program is coordinated with those efforts, and to have effective outreach procedures;

(continued…)

plan amendment hearing is whether the state's plan conforms to the requirements of the SCHIP statute and implementing regulations. *See* 42 U.S.C. § 1316(a)(2) (before state plan may be disapproved, state is entitled to hearing "on the issue of whether such plan conforms to the requirements for approval under [relevant statutory authority]"); *see also* 42 C.F.R. § 92.11 ("A State need meet only Federal administrative or programmatic requirements for a plan that are in statutes or codified regulations."). Although the letter does not explicitly state that New York will have the opportunity to challenge the policies contained in the SHO Letter, such opportunity is implicit, as New York will have the opportunity to argue that its plan amendment complies with existing statutory and regulatory requirements notwithstanding that it does not meet all of the terms of the SHO Letter – in other words, that the policies outlined in the SHO Letter are not a valid interpretation or means of enforcing those requirements. *See* 42 C.F.R. § 430.88(d)(4) (requiring hearing officer to provide each party "an opportunity . . . to refute facts and arguments advanced on either side of the issues").

Plaintiffs also cite various other informal communications they have had with CMS (many of them conference calls) in which they say that the agency "has been unwilling to consider any change in the requirements of the August 17 letter." Pls.' Br. at 24. But even assuming plaintiffs' one-sided characterizations of these conversations are accurate, these informal communications are just that – informal communications – and hardly constitute a definitive

---

- Whether the State has met the requirements to have reasonable procedures in place to ensure that health benefits coverage provided under the State plan do not substitute for coverage provided under group health plans, consistent with section 2102(b)(3)(C) of the Act as implemented by Federal regulations at 42 C.F.R. 457.805. . . . .

Declaration of Judith Arnold, Ex. 12 at 1-2.

body of agency practice. The issues in this case are not of a kind that should turn on who said what over the telephone and what they must have meant. *See Nat'l Audubon Soc'y v. Dep't of Navy*, 422 F.3d 174, 198 (4th Cir. 2005) ("Courts should not conduct far-flung investigations into the subjective intent of an agency."). The agency's practice is instead properly evaluated on the basis of final, binding decisions. *See Reliable*, 324 F.3d at 733 (finding it irrelevant that the agency "has already brought administrative proceedings against several other manufacturers . . . and has taken the position in those proceedings that sprinkler heads are 'consumer products,'" given that none of these administrative proceedings had proceeded to a final decision); *see also American Trucking Ass'ns, Inc. v. ICC*, 747 F.2d 787, 790 (D.C. Cir. 1984) (Scalia, J.) (dismissing procedural challenge to policy statement as unripe because the "concrete results" of adjudications made pursuant to the statement were "highly pertinent if not utterly indispensable to the resolution of the question" before the court). *cf. McLouth Steel Prods. v. Thomas*, 838 F.2d 1317, 1321 (D.C. Cir. 1988) (evaluating rulemaking challenge based on agency practice as reflected in final administrative decisions).

Moreover, whatever representations CMS staff made in the course of the informal communications cited by plaintiffs has been superseded by more recent CMS guidance. The follow-up guidance recently sent to all states, as well as the technical assistance recently provided to Rhode Island, are more definitive and up-to-date than any of the communications on which plaintiffs rely. And this guidance squarely reflects the position that CMS will hear states out on any proposed alternatives to the procedures and assurances described in the SHO Letter. *See supra* at 3-6.

In short, given that agency practice concerning the SHO Letter remains a work in progress that is not yet reflected in any pattern of final adjudicative decisions, plaintiffs' proce-

dural claim is unripe insofar as it rests on speculation about how CMS will treat the SHO Letter in rendering such decisions. Thus, not only is there reason to postpone judicial review of plaintiffs' substantive claim, but "the court has a genuine interest in postponing review of [their] procedural claim, too. . . . In addition, judicial economy favors considering all challenges . . . , both substantive and procedural, in one proceeding." *Nat'l Ass'n of Regulatory Util. Comm'rs v. DOE*, 851 F.2d 1424, 1430 (D.C. Cir. 1988).

3. Withholding Review Will Not Impose Hardship on the Plaintiffs

Finally, the case is unripe because the SHO Letter does not create any "direct and immediate dilemma" for the plaintiffs, as is required to establish hardship for ripeness purposes. Although plaintiffs claim that they are faced "now" with the choice "to comply with Defendant's new and draconian rules or forfeit federal funding for a significant population of children," Pls.' Br. at 19, this assertion does not withstand close scrutiny. No state can be required to comply with the SHO Letter without the occurrence of further administrative process.

Indeed, for states whose currently approved plans do not extend coverage above 250% FPL,[5] the SHO Letter does not force them to make any change whatsoever to their currently ap-

---

[5] In its initial brief, defendant grouped Washington with Illinois and New York as states whose currently approved plans do not extend coverage above 250% FPL. Defendant did so based on plaintiffs' complaint, which alleges that, as of June 2007, Washington's plan has provided coverage to individuals "between 200 to 250% of the federal poverty level." *See* Compl. ¶ 28. However, as plaintiffs indicate in their brief, Pls.' Br. at 19 n.1, the definition of income in Washington's current state plan excludes income through deductions in addition to disregards. Once deductions are factored in, Washington's plan does effectively extend coverage above 250% FPL, such that it is among the states to which the SHO Letter is addressed.

Defendant's initial brief was also mistaken in representing that CMS has not yet decided whether the SHO Letter applied to Maryland given that its program is an extension of its Medicaid program. Again, this representation was based on plaintiffs' characterization of Maryland's program in their complaint as an extension of its Medicaid program, *see* Compl. ¶ 25. However, as plaintiffs point out in their brief, Pls.' Br. at 20, Maryland has received communications from (continued…)

proved plans. For years, at their own choosing, these states have limited coverage under their plans to levels below 250% FPL; thus, the SHO Letter hardly thrusts upon them a sudden disruption of the *status quo.* It is quite a leap for plaintiff Illinois, in particular, to claim that it faces a "direct and immediate dilemma" between compliance with the SHO Letter and "forfeiting" federal funding, when the state has chosen to operate its program for ten years without extending coverage even above 200% FPL, has not sought to amend its plan to provide coverage above 250% FPL to date, and can only claim to be considering such an amendment at some unspecified date in the future. *See* Compl. ¶¶ 33-37.

It is true that plaintiff New York is actively seeking to amend its plan to expand coverage above 250% FPL, and that its proposed amendment has been initially denied by the agency, prompting New York to invoke its right to a reconsideration hearing. As long as administrative remedies remain available to New York, however, it cannot claim that its only choice is to comply with the SHO Letter's terms immediately or to give up the additional federal funding it seeks. Any state whose amendment is initially denied by CMS has the option of continuing to seek approval of its amendment through the reconsideration process – an option that New York has chosen to exercise. *See Reliable*, 324 F.3d at 733 ("So long as Reliable retains the opportunity to convince the agency . . . , it makes no sense for a court to intervene. It conserves both judicial

---

CMS requesting its compliance with the SHO Letter. The reason is that Maryland's program is a special type of Medicaid program – a demonstration program authorized by federal waiver under § 1115 of the Social Security Act. The Secretary has broad authority to attach conditions to such waiver programs, *see* 42 U.S.C. § 1315(a), and the SHO Letter itself indicates that it is intended to apply to such programs. *See* SHO Letter at 2 ("We expect affected States to amend their SCHIP state plan (or 1115 demonstration) in accordance with this review strategy . . . .").

The defendant regrets these oversights. But neither significantly alters the hardship analysis.

and administrative resources to allow the required agency deliberative process to take place before judicial review is undertaken.").

To be sure, the issuance of the SHO letter has raised a sharp dispute between CMS and New York, making the administrative process lengthier and more complicated than it otherwise might be. Thus, New York complains that it was not able to obtain approval for its amendment by September 2007, as it originally expected. Pls.' Br. at 15. But such delay is simply part of the administrative process and cannot establish hardship for ripeness purposes. *See* Def.'s Br. at 25-26. Were the law otherwise, parties would never have an incentive to exhaust the administrative process in the event of serious disagreements with the agency – which is precisely when ripeness concerns are most acute. *See Air Espana*, 165 F.3d at 152 (ripeness doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies") (quoting *Abbott Labs.*, 387 U.S. at 148-49).

Moreover, Congress specifically anticipated the scenario that New York now faces and chose not to provide the option of immediate judicial review when a state's plan amendment is initially denied. Instead, it provided a mechanism by which the state can recoup any funds improperly denied to it during the time it takes to complete the reconsideration process. In the Medicaid judicial review provision incorporated by reference in the SCHIP statute, Congress instructed that "[a]ction pursuant to an initial determination of the Secretary . . . shall not be stayed pending reconsideration, but in the event that the Secretary subsequently determines that his initial determination was incorrect he shall certify restitution forthwith in a lump sum of any funds incorrectly withheld or otherwise denied." 42 U.S.C. § 1316(c). Thus, Congress recognized that a state seeking reconsideration of an initial denial of a plan amendment would have to do without the denied federal funding while it completed the reconsideration process; but Congress did not

consider such delay to warrant allowing the state to proceed immediately to court. Instead, Congress required exhaustion of the administrative process while providing the state with a right to restitution should it ultimately prevail. New York cannot be heard to complain of hardship from funding delays that Congress accepted as part of the administrative process it had designed.[6]

As for states whose currently approved plans already provide coverage above 250% FPL, these states, too, do not face any direct and immediate dilemma entailing the loss of program funding. As explained above, only a final determination of non-compliance, duly made at the conclusion of a compliance proceeding initiated by CMS, could put these states in such a dilemma.[7] In contrast to *Abbott Laboratories* and the related cases cited by plaintiffs, *see* Pls.' Br. at 19-20, here the states run no risk of being sanctioned for their present conduct. The only risk

---

[6] The same arguments extend to the derivative claims of hardship alleged by *amicus* Healthcare Association of New York State (HANYS), which argues that CMS's delay in approving New York's program expansion is harming the state's uninsured children as well as the state's medical community as a whole. Whenever a state proposes an amendment to expand coverage, those who stand to benefit from the expanded coverage can claim to be harmed by any delay entailed in the amendment-approval process. Were such harm sufficient to warrant immediate review, no state would ever be required to exhaust that process as Congress has prescribed. Moreover, arguments premised on such harm are especially attenuated here, given that, in the absence of federal approval, New York intends to expand coverage to 400% FPL using its own funds effective September 2008, *see* Pls.' Br. at 15. Thus, the expansion of coverage desired by HANYS will soon occur, regardless of what CMS does; the only question is what share of that expansion will be funded by the federal government.

[7] State programs, such as Maryland's, that extend coverage to children above 250% FPL through Medicaid demonstration programs authorized by federal waiver, *see supra* n.5, present a special case. In addition to being potentially subject to compliance proceedings (under the terms and conditions of the waiver agreement), such programs are authorized for limited periods and thus are subject to periodic reviews to determine whether the program authorization should be renewed. *See* 42 U.S.C. § 1315(e). Non-renewal could result in a loss of program funding, but a non-renewal decision can be made only after an extensive, structured negotiation process between federal and state officials. *Id.* § 1315(f). Furthermore, in the event of non-renewal, the state may have options to operate its program without demonstration authority. In any event, the mere threat of non-renewal cannot constitute hardship for ripeness purposes, any more than the mere threat of future compliance proceedings.

that states run is that CMS will bring *future* administrative proceedings in which the agency may decide to withhold funds *prospectively* if the state does not come into compliance with the SHO Letter.

There is no certainty that CMS will initiate compliance proceedings against any particular plaintiff here whose current plan extends coverage above 250% FPL. The SHO Letter merely notifies affected states of this possibility. Further, in the event that CMS does choose to initiate a compliance proceeding, the state would have the opportunity for a hearing before any funding is withheld, and the subsequent opportunity to seek judicial review of any adverse final decision. Accordingly, none of the plaintiffs faces any immediate dilemma justifying pre-enforcement review. *See Reliable*, 324 F.3d at 733 ("We do not know whether the agency will bring administrative enforcement proceedings against Reliable. If the agency does decide to pursue a complaint, Reliable will be afforded a hearing in which it will have ample opportunity to convince the agency against the assertion of regulatory jurisdiction and create a record for judicial review should that later be deemed necessary.").

B. The SCHIP Statute Precludes Jurisdiction

As explained in defendant's initial brief, even if plaintiffs' complaint were ripe, jurisdiction would be precluded by 42 U.S.C. § 1316(a), which specifies that any adverse determination with respect to a state's plan – whether a denial of a proposed plan amendment, or a determination that a state's current plan is in non-compliance – is subject to judicial review in *circuit* court *after* a final administrative decision has been made. *See* 42 U.S.C. § 1316(a)(3).[8] Plaintiffs con-

[8] Contrary to plaintiffs' suggestion that § 1316(a)(3) governs judicial review only of final denials of plan *amendments*, Pls.' Br. at 27-28, the statute also governs judicial review of final determinations that a state's *current* plan is in non-compliance. The provision states that any state dissa- (continued…)

tend that § 1316 does not control here, arguing that they "do not seek approval of their respective state plans, but rather collaterally challenge the process by which Defendant reviews such plans." Pls.' Br. at 29. However, "calling an issue 'collateral' does not make it so." *Eastern Bridge, LLC v. Chao*, 320 F.3d 84, 90-91 (1st Cir. 2003). At bottom, plaintiffs challenge CMS's authority to disapprove state plan material if it does not meet certain conditions. This is precisely the sort of plan-conformity issue that Congress intended for courts to review under § 1316(a).

The Supreme Court rejected a similar attempt to evade the reach of a statutory review provision in *Heckler v. Ringer*, 466 U.S. 602 (1984). There, several individuals sought to challenge a Medicare policy under which they stood to be denied reimbursement for a particular type of surgery were they to exhaust the administrative claims process. *Id.* at 610-11. The plaintiffs did not directly seek reimbursement in the litigation, and they "[a]rguably . . . assert[ed] objections to the Secretary's 'procedure' for reaching her decision – for example, . . . they challenge[d] her alleged failure to comply with rulemaking requirements of the APA." *Id.* at 614. Nonetheless, the Court found that their claims in the litigation were "inextricably intertwined" with their claims for benefits, noting that "the relief that respondents seek to redress their supposed 'procedural' objections is the invalidation of the Secretary's current policy." *Id.* Thus, the

---

tisfied with the Secretary's denial of a plan amendment after a reconsideration hearing *or* "a final determination of the Secretary under section 304, 1204, 1354, 1384, or 1396c of this title" may obtain review "of such determination" in circuit court. 42 U.S.C. § 1316(a)(3). The referenced series of statutory provisions concern non-compliance determinations in the context of Medicaid and other programs. Because the SCHIP statute states that the provisions of § 1316 shall apply to the program "in the same manner as they apply to States under [Medicaid]," it follows that SCHIP non-compliance determinations are subject to judicial review in the manner prescribed by § 1316(a)(3). The SCHIP regulations make this clear, as they provide that "any State dissatisfied with the Administrator's final determination on approvability of plan material . . . *or compliance with Federal requirements* . . . has a right to judicial review" under the terms of § 1316(a)(3). 42 C.F.R. § 457.208(a) (emphasis added).

Court held, "it makes no sense" to construe plaintiffs' claims "as anything more than, at bottom, a claim that they should be paid for their . . . surgery." *Id.* As such, those claims had to be pursued through the statutorily prescribed review process, regardless of how they were styled:

> We conclude that all aspects of respondents' claim for benefits should be channeled first into the administrative process which Congress has provided for the determination of claims for benefits. We, therefore, disagree with the Court of Appeals' separation of the particular claims here into 'substantive' and 'procedural' elements. We disagree in particular with its apparent conclusion that simply because a claim somehow can be construed as 'procedural,' it is cognizable in federal district court by way of federal-question jurisdiction.

Id. at 614. Notably, even though one of the *Ringer* plaintiffs (a surgeon) had not even performed the surgery at issue yet, the Court found that he was "clearly seeking to establish a right to future payments" and thus he too had to proceed under the statutory review scheme, which did not allow "federal judges to issue such advisory opinions." *Id.* at 621-22.

As in *Ringer*, plaintiffs' claims here are inextricably intertwined with agency determinations governed by a statutory review scheme – namely, determinations concerning the approvability of state plan material. In essence, plaintiffs seek an advisory opinion on CMS's authority to disapprove a state plan or plan amendment in the future based on the review strategy described in the SHO Letter. Indeed, in their prayer for relief, plaintiffs specifically "ask this Court to enjoin HHS from disapproving any state child health plan or state plan amendment using the criteria stated in CMS's August 17, 2007 letter." Compl. at 22.[9] The claims that plaintiffs raise here are the same the claims that they would raise in any plan-amendment or plan-compliance pro-

[9] The *Miles* plaintiffs go even further in their complaint, as they seek an order that would "remand" New York's plan amendment to the Secretary, "with instructions to, within 15 days of the Court's order, complete his review of the State plan amendment consistent with the broad flexibility accorded to the State by [the SCHIP statute] and without regard to the letter of August 17, 2007." *Miles* Compl. at 17.

ceeding involving the SHO Letter – as evidenced by New York's ongoing administrative proceeding, in which New York has made plain that it intends to argue that the SHO Letter policies "exceed the authority vested in the Secretary" and "constitute illegally promulgated regulations in violation of the notice and comment provisions of the [APA]." First Turner Decl., Ex. B., at 2.

Hence, plaintiffs' claims cannot be fairly characterized as "collateral." Their claims are integral to their disagreement with the agency over whether their current plans or contemplated plan amendments conform to federal requirements. Those claims must be channeled into the review process Congress provided for resolving such disagreements. *See Standard Oil*, 449 U.S. at 246 (issues are not "collateral" where they "will merge in" the agency's "decision on the merits").

The principal case relied on by plaintiffs, *McNary v. Haitian Refugee Center, Inc.*, 498 U.S. 479 (1991), is not to the contrary. In that case, unlike in *Ringer* or here, judicial review was clearly unavailable under the statutory review scheme for the claims at issue. *Id.* at 496. The Supreme Court's *Thunder Basin* decision distinguished *McNary* on this basis, explaining that *McNary* involved procedural due process claims that were "wholly 'collateral'" to the tightly limited statutory review scheme, such that the plaintiffs "would not as a practical matter be able to obtain meaningful judicial review" unless they were permitted to bring suit outside the confines of that scheme. *See Thunder Basin*, 510 U.S. 200, 213 (1994). The *Thunder Basin* Court contrasted such claims with the claims of the mining company before it, which "at root require[d] interpretation of the parties' rights and duties . . . under the Mine Act." 510 U.S. at 213. On this basis, the Court held that *McNary* was inapposite and that the company's claims were governed by the Mine Act's statutory review scheme. *See Fornaro v. James*, 416 F.3d 63, 68 (D.C. Cir.

2005) ("[T]he statutorily mandated administrative process [in *McNary]* did not address the sort of procedural and constitutional claims the *McNary* plaintiffs sought to bring in district court, and so did not preclude them. Here there is a far closer connection between the relief sought in the judicial action and that available in the administrative process."); *Chan v. Reno*, 916 F. Supp. 1289, 1306 (S.D.N.Y. 1996) ("*McNary*'s general thrust was to vest the district courts with jurisdiction only where 'the administrative appeals process does not address the kind of procedural and constitutional claims respondents bring.'") (quoting *McNary*, 498 U.S. at 491).

Significantly, the *Thunder Basin* Court reached this holding even though, contrary to plaintiffs' claim that the mining company there merely sought "review of a specific order of the Mine Safety and Health Administration," Pls.' Br. at 29, in fact the company also brought a due process challenge to the agency's *procedures* for reviewing that order. *See Thunder Basin*, 510 U.S. at 214. Even as to this procedural claim, the Court found that the Mine Act's judicial review scheme controlled, because the claim could be meaningfully reviewed within that scheme. As the Court explained, the agency was competent to adjudicate the plaintiff's procedural claim in the course of administrative proceedings; and "[e]ven if this were not the case," the claim could "be meaningfully addressed in the Court of Appeals" on judicial review. *Id.* at 215.

Hence, *Thunder Basin* controls here, not *McNary*.[10] As in *Thunder Basin*, plaintiffs' claims can be meaningfully reviewed within the statutory scheme Congress established in

[10] In addition to *McNary*, plaintiffs mistakenly rely on *Bowen v. City of New York*, 476 U.S. 467 (1986), Pls.' Br. at 29, which did not even involve the issue of whether district court jurisdiction was statutorily precluded. Instead, there was no dispute in *Bowen* that plaintiffs were entitled to seek review in district court after exhausting their administrative remedies, *id.* at 472; the only issue was whether the district court could waive plaintiffs' obligation to exhaust given the nature of their claims (which asserted affirmative agency misconduct), *id.* at 474-75. Waiving exhaustion is a far cry from allowing judicial review in a different forum than the one prescribed by (continued…)

§ 1316(a). Plaintiffs are simply wrong in claiming that that § 1316(a) "provides only for review of a particular state plan, not for the collateral review of HHS regulations that the Plaintiff States seek." Pls.' Br. at 30. Section 1316(a) provides a perfectly adequate vehicle for seeking review of the *validity* of CMS's program requirements – not simply their application in a given case. Indeed, the legislative history of the provision indicates that Congress intended it to be used as a vehicle for such challenges. *See* 111 Cong. Rec. 3,068 (1965) (remarks of Sen. Javits) ("Court review would involve a determination of whether an amendment to the existing plan proposed by the State *or a new administrative requirement promulgated by the Federal agency* conformed with the intent of the Federal statute.") (emphasis added), *quoted in N.J. v. HHS*, 670 F.2d 1262, 1276 (3d Cir. 1981). Moreover, § 1316(a) has in fact been used as such a vehicle: courts of appeal have specifically reviewed cases under the provision involving challenges to the validity of federal requirements – including challenges to the agency's issuance of policies without notice-and-comment rulemaking. *See W. Va. v. Thompson*, 475 F.3d 204, 210 (4th Cir. 2007) (reviewing under § 1316(a) whether criteria for CMS's denial of state's Medicaid plan should have been issued through rulemaking); *N.J. v. HHS*, 670 F.2d at 1276 (reviewing under § 1316(a) whether a new administrative requirement set forth in a "program instruction" interpreting an existing regulation was consistent with the Medicaid statute). Thus, contrary to plaintiffs' assertion that they would be "cut off" from judicial review were § 1316(a) construed to govern their claims, Pls.' Br. at 30, plaintiffs plainly could obtain judicial review on their claims were they to follow the

---

Congress, as plaintiffs seek to do here. *See Fornaro*, 416 F.3d at 68 (distinguishing *Bowen* on similar grounds: "Allowing an alternative route to relief in the district court because plaintiffs frame their suit as a systemwide challenge . . . would substitute an entirely different remedial regime for the one Congress intended to be exclusive, rather than, as in *Bowen*, simply alter the timing of the congressionally mandated judicial review.").

process that § 1316(a) prescribes. Under *Thunder Basin*, it follows that they are precluded from obtaining review in any other manner.

Practical considerations underscore this conclusion. Were plaintiffs' position accepted, the upshot would be that a state could challenge CMS's requirements in district court and circuit court *simultaneously*, so long as in district court the state purported to challenge those requirements "on their face" without specifically seeking approval of its plan. This scenario is not even theoretical here, given the impending hearing on New York's plan amendment. Should New York's amendment be finally denied in that administrative proceeding, New York could seek immediate judicial review under § 1316(a) and raise in circuit court the same challenges presented in this action – potentially while it is still pending before this Court. *Cf. American Trucking Ass'ns*, 747 F.2d at 791 ("[T]he availability of a more appropriate medium for our review is demonstrated by the fact that a case involving a challenge to the policy here in dispute, but arising from the concrete application of that policy in a particular license proceeding, has already been argued before this court.").

Section § 1316(a) should be construed to preclude such an outcome. "It is highly unlikely that Congress intended to create a scheme involving multiple avenues of review and potential contradictory results." *NRDC v. Johnson*, 461 F.3d 164, 174 (2d Cir. 2006); *see also Sun Enters. v. Train*, 532 F.2d 280, 287 (2d Cir. 1976) ("[T]here is a strong presumption against the availability of simultaneous review in both the district court and the court of appeals."). Precisely to avoid such conflicts, the courts have held that, when a statute includes "a specific statutory grant of jurisdiction to the court of appeals, it should be construed in favor of review by the court of appeals." *NRDC v. Abraham*, 355 F.3d 179, 193 (2d Cir. 2004) (citing, *inter alia*, *Nat'l Parks & Conservation Ass'n v. FAA*, 998 F.2d 1523, 1529 (10th Cir.1993) ("If there is any ambiguity as

to whether jurisdiction lies with a district court or with a court of appeals we must resolve that ambiguity in favor of review by a court of appeals."); *Ind. & Mich. Elec. Co. v. EPA*, 733 F.2d 489, 491 (7th Cir.1984) (invoking "the judge-made presumption in favor of court of appeals review in doubtful cases")).[11] Accordingly, given that § 1316 specifically establishes a route to review in circuit court, through which plaintiffs could seek review of the claims presented here after a final administrative decision, pre-enforcement review in this Court is precluded.

C. Plaintiffs Cannot Proceed under the APA Given the Availability of an Adequate Alternative Judicial Remedy

Finally, plaintiffs have no answer to the argument that review under the APA, on which their complaint is based, is barred given the availability of an adequate alternative judicial remedy under § 1316(a). *See* 5 U.S.C. § 704 (limiting APA review to final agency action "for which there is no other adequate remedy in a court"). Plaintiffs merely reiterate their argument that § 1316(a) "provides only for review of a particular adjudication of a state plan, and not of the regulations governing that adjudication." Pls.' Br. at 31. As explained, this argument is simply misinformed. Plaintiffs indisputably can challenge the validity of CMS's requirements in a petition for review brought under § 1316(a). And in light of that statutory route to judicial review, suit under the APA is precluded. *See generally Bowen v. Massachusetts*, 487 U.S. 879, 903 (1988) (APA right to review was not intended to displace "special statutory procedures relating to specific agencies").

Plaintiffs further argue that, "[e]ven if the administrative process allowed review of Defendant's illegally promulgated regulations, such review does not preclude judicial review where

[11] While plaintiffs note that neither the SCHIP statute nor § 1316 contain an express provision that the review provisions of § 1316(a) are exclusive, Pls.' Br. at 30 n.3, the foregoing cases make clear that such exclusivity is presumed. *See also* Def.'s Br. at 27-28 & n.7.

the administrative body has predetermined the issues before it." Pls.' Br. at 31. Yet this argument conflates the adequacy of plaintiffs' *administrative* remedies with the adequacy of their alternative *judicial* remedies. Only the latter need be adequate for APA review to be precluded. Thus, even assuming that CMS has completely "predetermined" plaintiffs' claims, such that it would be futile for them to seek administrative approval of their state plans in light of the SHO Letter – an assumption that is not warranted, *see supra*, Point I.A.1.a –, it hardly follows that plaintiffs should be entitled to sue immediately in *district* court *under the APA*. Futility speaks only to whether plaintiffs should be able to skip the administrative process, not the forum in which they may proceed to obtain judicial review. *See Fornaro*, 416 F.3d at 68. If plaintiffs want to test their futility claims, they could each file petitions for review right now *in circuit court* and attempt to establish jurisdiction *under § 1316(a)(3)* on the theory that CMS has constructively adjudicated their state plan material. *Cf. N.J. v. HHS*, 670 F.2d at 1277-78 (allowing state to obtain circuit court review under § 1316(a) without exhausting administrative remedies given that exhaustion would have been futile). But plaintiffs have no argument for why they should be able to bypass the statutory review scheme *entirely*, by seeking review in this Court.[12]

[12] Moreover, plaintiffs cannot argue that § 1316(a) fails to provide an adequate alternative remedy based on the notion that the remedy the statute provides is somehow more cumbersome than district court review under the APA. The test under the APA is not whether plaintiffs have an "equally effective remedy"; it is whether they have "an adequate one." *Am. Disabled for Attendant Progs. Today v. HUD*, 170 F.3d 381, 390 (3d Cir. 1999); *see also Council of & for the Blind of Del. County Valley, Inc. v. Regan*, 709 F.2d 1521, 1532-33 (D.C. Cir. 1983) (en banc) ("[E]ven if, as appellants argue, a nationwide suit would be *more effective* than several [separate suits brought under the statutory review scheme], we hold that the remedy provided by Congress is *adequate* . . . .") (emphasis in original).

POINT II

THE SHO LETTER IS NOT A LEGISLATIVE RULE

As the foregoing demonstrates, plaintiffs' rulemaking challenge is unripe; and even if it were ripe, it could only be pursued in circuit court under § 1316(a). Nonetheless, were the Court to reach the merits of plaintiffs' rulemaking claim, the Court should reject it. The SHO Letter is not a legislative rule, but is instead a general statement of policy or interpretive rule not subject to the APA's rulemaking requirements. Plaintiffs present essentially two arguments to the contrary. They contend that: (1) the letter's language and the agency's subsequent conduct evidences an intention to establish a legally binding norm that constrains the agency's own discretion; and (2) the policies in the SHO Letter cannot be derived from existing statutory and regulatory requirements. Both arguments fail.

A. The SHO Letter Lacks Binding Legal Effect

As plaintiffs note, in distinguishing legislative from non-legislative rules, courts have generally focused on whether the statement at issue "imposes a legally binding norm" that "limits the agency's own discretion." Pls.' Br. at 34. As set forth above, the SHO Letter does not have any binding legal effect, because it is not final agency action from which legal consequences directly flow, but is instead only a statement of how the agency intends to proceed in future adjudications of state plan material. Any legally binding determinations would be made through such adjudications, on a case-by-case basis. *See supra*, Point I.A.1.

A review of first principles helps to elucidate why the agency can permissibly proceed in this manner, without the need for a rulemaking. First, it is well settled APA law that an agency can impose binding legal obligations in one of two ways: either through rulemaking or adjudication. *E.g.*, *SEC v. Chenery*, 332 U.S. 194, 202-03 (1947). The choice between the two modes of policymaking lies with the agency. Even where an agency seeks to implement a policy that

represents a significant change from past practice, the agency can choose to do so through the adjudicative process rather than rulemaking. *See, e.g.*, *NLRB v. Bell Aerospace*, 416 U.S. 267, 295 (1974) ("[T]he Board is not precluded from announcing new principles in an adjudicative proceeding and . . . the choice between rulemaking and adjudication lies in the first instance within the Board's discretion."); *Mobil Exploration & Producing N. Am. v. FERC*, 881 F.2d 193, 198 (5th Cir. 1989) ("Adjudication can be used to announce new principles even if the principles involve a change from past policies."); *see also W. Va. v. Thompson*, 475 F.3d at 210 (recognizing agency's authority to choose adjudication rather than rulemaking in context of CMS administrator's review of Medicaid state plan amendment); *Alaska Dep't of Health & Social Servc. v. CMS*, 424 F.3d 931, 939 (9th Cir. 2005) (same). It is true that an agency cannot announce new principles in an adjudication that contravene existing regulations, for an agency's regulations are legally binding on the agency and typically cabin the discretion it may exercise in an adjudication. *See Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995). To the extent consistent with existing regulations, however, an agency is free to depart from its past practice in any policy it chooses to establish through adjudication.

Importantly, where an agency opts to make policy through adjudication rather than rulemaking, the regulated community is not thereby prevented from having a say in the administrative process. Their participation is merely channeled into a different type of agency proceeding – the adjudication, which allows for the full airing and consideration of the views of the regulated party whose claim is being adjudicated (as well as any other interested members of the regulated community able to participate as intervenor or *amicus*). Again, it is the agency's choice whether to solicit the views of the regulated community in this manner as opposed to the notice-and-comment process that marks a rulemaking. As the Supreme Court stated in *Bell Aerospace*:

> It is true, of course, that rulemaking would provide the Board with a forum for soliciting the informed views of those affected in industry and labor before embarking on a new course. But surely the Board has discretion to decide that the adjudicative procedures in this case may also produce the relevant information necessary to mature and fair consideration of the issues. Those most immediately affected . . . are accorded a full opportunity to be heard before the Board makes its determination.

416 U.S. at 295.

Nor does the agency's choice to proceed through adjudication rather than rulemaking somehow insulate the agency's newly announced policy from judicial review. "To the extent that the policy . . . represents a generalized principle that can be successfully attacked, the same principle will be reflected in individual adjudications, and can be addressed, root and branch, in that context." *American Trucking Ass'ns*, 747 F.2d at 790; *cf. N.Y.C. Employees' Retirement Sys. v. SEC*, 45 F.3d 7, 14 (2d Cir. 1995) ("'A non-legislative rule's capacity to have a binding effect is limited in practice by the fact that agency personnel at every level act under the shadow of judicial review.'") (quoting *Amer. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1111 (D.C. Cir. 1993)).

Concomitant to an agency's authority to make new policy through adjudication, an agency may also give the public advance notice of its intention to do so in *future* adjudications – even if the practical consequence may be to induce a voluntary change in conduct on the part of regulated entities before such adjudications occur. This is the purpose of a general statement of policy or interpretive rule; it serves to "announce[] the course which the agency intends to follow in future adjudications," in order to "facilitate[] long range planning within the regulated industry." *Pac. Gas & Elec. v. FPC*, 506 F.2d 33, 38 (D.C. Cir. 1974). As long as parties will have a meaningful opportunity in such adjudications to challenge the agency's policy before it is applied to them, the agency's announcement of the policy prior to its application cannot itself be construed as a "legally binding norm" requiring a rulemaking. Otherwise, the agency's prerogative to

make policy through adjudication – and to publicly announce that intention before adjudications commence – would be meaningless. That is the core teaching of the D.C. Circuit's decision in *Pacific Gas*, and to the extent that plaintiffs rely on case law inconsistent with it, that case law should be rejected as unpersuasive. *See Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 952 (D.C. Cir. 1987) (Starr, J., concurring in part and dissenting in part) ("Inasmuch as our decisional law over the last decade avowedly reflects considerable uncertainty in discerning the line between agency pronouncements that are 'law' and those that are 'policy,' it seems advisable to return to the pristine teaching of *Pacific Gas.*") (citation omitted); *see also* William Funk, *When Is a "Rule" a Regulation? Marking a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 ADMIN L. REV. 659 (2002) (criticizing trends in case law concerning distinction between legislative and non-legislative rules and proposing simplifying approach).[13]

Given that it does not contravene any of the foregoing principles, the SHO Letter qualifies as a general statement of policy or interpretive rule. Contrary to plaintiffs' contention that the SHO Letter "employs mandatory language that demonstrates a *present* intent to bind states," Pls.' Br. at 36 (emphasis added), the letter does not impose any present legal obligations on the states. Any categorical language in the letter is used only to describe the review strategy that CMS intends to apply in *future* adjudications of state plan material, which is the only mechanism through which the policies in the SHO Letter can be given binding legal effect. *See supra* Point

[13] Courts have frequently remarked on the lack of clarity and consistency in the case law concerning legislative versus non-legislative rules. *See, e.g.*, *Concourse Rehab. & Nursing Ctr. v. DeBuono*, 179 F.3d 38, 46 (2d Cir. 1999) (noting that distinction between interpretive rules and legislative rules "has been described by courts and commentators as 'fuzzy,' 'tenuous,' 'blurred,' 'baffling,' and 'enshrouded in considerable smog'"); *Ctr. for Auto Safety v. NHTSA*, 452 F.3d 798, 807 (D.C. Cir. 2006) ("As the case law reveals, it is not always easy to distinguish between those 'general statements of policy' that are unreviewable and agency 'rules' that establish binding norms or agency actions that occasion legal consequences that are subject to review.").

I.A.2.[14] Thus, "[t]he policy statement makes it clear that the decisions have not yet been taken." *Pub. Citizen*, 940 F.2d at 682. Again, nothing prevents the agency from announcing in advance the approach it intends to follow in future adjudications – which by definition involves announcing what the agency intends to "require" from regulated parties. *See Pacific Gas*, 506 F.2d at 41 ("Although the Commission is free to establish a binding substantive rule, the Commission apparently intends to establish its curtailment policies by proceeding through individual adjudications. Order No. 467 merely announces the general policy which the Commission hopes to establish in subsequent proceedings.").[15]

Moreover, nothing in the SHO Letter indicates that the policies it announces are binding on the agency itself, in the same sense that a regulation can be binding on an agency and insusceptible to challenge in individual administrative proceedings. *See Pacific Gas*, 506 F.2d at 38 (hallmark of a legislative rule is that it has the force of law in administrative proceedings and "is not generally subject to challenge"); *see also McLouth Steel Prods.*, 838 F.2d at 1320 (statement is legislative rule if it "denies the decisionmaker discretion"). Indeed, it is hard to see how the letter could be binding in this sense. It is not a directive to be carried out by lower-level officials. CMS regulations make clear that a determination that a state's plan or plan amendment

---

[14] The text of the letter speaks only to what CMS "will" expect of the states in reviewing state plan material in the future. *See* SHO Letter at 2 ("we *will expect* . . . the specific crowd-out prevention strategies identified in the State child health plan to include . . ."); *id*. ("we *will ask* for such a State to make the following assurances . . ."); *id.* ("CMS *will apply* this review strategy to SCHIP state plans") (all emphases added).

[15] Plaintiffs' attempt to distinguish *Pacific Gas* and to compare this case instead to *Columbia Broadcasting System v. United States*, 316 U.S. 407 (1942), *see* Pls.' Br. at 44-45, is meritless. *Columbia Broadcasting* is distinguishable for the same reasons explained in *Pacific Gas* itself: it involved a challenge to actual *regulations* that could not be challenged in future adjudicative proceedings and that, like the regulations in *Abbott Laboratories*, had an immediate binding effect on regulated parties. *See Pacific Gas*, 506 F.2d at 42-43.

does not conform to federal requirements can only be made by the CMS Administrator, and only after "first consulting the Secretary." *See* 42 C.F.R. § 457.150(c).[16] Thus, the CMS Administrator, working with the Secretary, has the ultimate authority to make the decisions that the SHO Letter concerns. While the SHO Letter stakes out the review strategy the Administrator currently intends to use in making those decisions, the Administrator retains the inherent discretion to follow a different approach in any particular case. The SHO Letter does not – and simply cannot – take that discretion away. *See Pub. Citizen*, 940 F.2d at 682 (stating that whether agency intends to be bound by policy statement can sometimes be determined by "a simple reading of the document and study of its role in the regulatory scheme").

As to plaintiffs' argument based on agency "conduct," that argument similarly fails to establish that the policies in the SHO Letter are somehow legally binding upon the agency. As discussed above, *see supra* Point I.A.1.a, the conduct on which plaintiffs rely consists of preliminary and informal communications, which are not a reliable guide to agency practice. But in any event, some of the very communications plaintiffs cite suggest that the agency will exercise significant flexibility in applying the SHO Letter to specific state plans. And such flexibility is fur-

---

[16] Plaintiffs' brief erroneously states that plan-conformity adjudications by CMS are performed by HHS' Departmental Appeals Board ("DAB") (which they incorrectly refer to as the "Departmental Review Board"). Pls.' Br. at 32 n.4. The DAB is responsible for reviewing disallowance decisions, where a state administratively appeals a decision by CMS to disallow a state's claims to federal reimbursement for particular program expenditures. *See* 42 C.F.R. § 457.212; *see generally N.J. v. HHS*, 670 F.2d at 1270 (distinguishing disallowance proceedings, used to address routine audit exceptions, from plan-conformity proceedings, used to address problems in the state's plan as a whole). Plan conformity determinations, by contrast, are made by the CMS Administrator – both the initial determination and the final determination on reconsideration. *See* 42 C.F.R. §§ 457.203(a), 457.204(a). (Typically, however, a designee of the CMS Administrator presides at the reconsideration hearing, *see id.* § 430.66, and recommends a decision to the Administrator, who then issues his own decision after reviewing the recommendation, *see id.* § 430.102.)

ther evidenced in more recent administrative developments – particularly in the general follow-up letter sent to all states and the specific feedback given to Rhode Island. This superseding guidance leaves little doubt that the agency is able and willing to entertain alternative approaches to the policies contained in the SHO Letter in individual cases. Hence, it cannot be said that the agency's conduct to date establishes an intent to treat the SHO Letter as binding law. *See Pac. Gas & Elec.*, 506 F.2d at 40-43 (finding agency order to be a general statement of policy based significantly on subsequent clarification that order did "not mean that the parties may not propose or the commission may not adopt variations" from the policy set forth in the order); *see also Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 228 (D.C. Cir. 2007) ("There is nothing improper about an agency . . . relying on . . . new language to defend itself upon judicial review."); *Telecomm. Research & Action Ctr. v. FCC*, 800 F.2d 1181, 1186 (D.C. Cir. 1986) ("It is well established that a court, in determining whether notice and comment procedures apply to an agency action, will consider the agency's own characterization of the particular action.").

In short, neither the language of the SHO Letter nor the agency's related conduct to date establish that the letter itself is a *legally* binding document that constrains the agency's own discretion. While, assuredly, the letter gives advance notice to states of the approach the agency intends to take in future adjudications of state plans seeking to extend coverage above 250% FPL, and while states may voluntarily change their behavior in light of this advance notice, "this does not demonstrate that the guidelines have had *legal consequences*." *Ctr. for Auto Safety*, 452 F.3d at 811.[17]

[17] In this respect, plaintiffs' rulemaking challenge fails for the same reason that their finality arguments fail. Courts have noted the overlap between the two issues. *See, e.g.*, *Cement Kiln*, 493 F.3d at 226 & n.14.

B. The Policies in the SHO Letter Are Consistent with and Derive from Existing Statutory and Regulatory Requirements

As defendant has explained, a general statement of policy or interpretive rule does not itself impose binding legal requirements; instead, it informs the public as to how the agency intends to apply existing legal requirements that do have binding force. *See* Def.'s Br. at 34-35. Notwithstanding plaintiffs' various arguments to the contrary, *see* Pls.' Br. at 39-48, the SHO Letter meets this description. As the letter itself states, it is intended to "clarif[y] how [CMS] applies existing statutory and regulatory requirements." SHO Letter at 1. More specifically, the letter explains that the review strategy it describes is based on the states' existing obligations to provide coverage to uninsured, low-income children in "an effective and efficient manner" that is "coordinated with other sources of health benefits coverage" and that includes "reasonable procedures" to prevent crowd-out. *Id.* (citing provisions codified at 42 U.S.C. §§ 1397aa(a), 1397bb(b)(3)(C)&(E), and 42 C.F.R. § 457, Subpart H).

Plaintiffs err insofar as they construe these provisions as mere "reporting requirement[s]" that do not vest the agency with substantive decision-making authority, Pls.' Br. at 47. In particular, they err in contending that 42 C.F.R. § 457.805, which requires state plans to include "reasonable" crowd-out procedures, does not give the agency authority to require states to adopt particular crowd-out procedures over others. According to plaintiffs, "the regulations require only that states report what procedures they have determined, in their own discretion, to be reasonable. This flexibility gives *states* the discretion to determine what procedures are reasonable, not Defendant." Pls.' Br. at 41 (emphasis in original).

This view of the statutory and regulatory framework is untenable. A fundamental premise of the SCHIP program is that states must receive federal approval of their state plans as a precondition to spending federal dollars. *See* 42 U.S.C. § 1397ff(a)(1). The SCHIP statute thus

authorizes the agency to "establish a process for enforcing requirements under this subchapter," *id.* § 1397ff(d)(2), and to review state plans and amendments "to determine if they substantially comply with the requirements of this subchapter," *id.* § 1397ff(c)(1). This grant of enforcement authority would be rendered meaningless if the agency were limited to requiring the states to "report" the contents of their state plans.

It is of little moment that the statute and regulations are phrased in terms of requiring state plans to "describe" the procedures the state will use to meet program objectives. *See* Pls.' Br. at 47 (emphasizing language in 42 C.F.R. § 457.805 requiring state plans to "include a *description* of reasonable procedures" to prevent crowd-out); *see also* 42 U.S.C. § 1397bb (couching a variety of plan requirements in similar language). The point is that, for federal plan review to be meaningful, the agency must have the authority to evaluate whether the procedures described in a state plan will effectively meet relevant program objectives. In particular, as to 42 C.F.R. § 457.805, the agency, not the states, must have authority to determine whether a state's crowd-out procedures will "reasonabl[y] . . . ensure that health benefits coverage provided under the State plan does not substitute for coverage provided under group health plans." *Id.*

Given that the agency has discretion to exercise in determining what types of substitution procedures it will consider "reasonable," it has the derivative authority to issue general statements of policy describing "the manner in which the agency proposes to exercise [that] discretionary power." *See Pac. Gas*, 506 F.2d at 38 n.17 (quoting the Attorney General's Manual on the APA 30 n.3 (1947)). That is precisely what the SHO Letter does. The crowd-out policies it describes are policies that the agency can effectively require through the application of existing statutory and regulatory requirements to individual state plans.

For example, without issuing the SHO Letter, the agency could find, in the context of reviewing a state plan that extends coverage above 250% FPL, that the uninsurance period included in the plan is not long enough to offer reasonable assurance against crowd-out. Based on experience with crowd-out rates among similarly situated states, CMS could find that an uninsurance period of at least 12 months is necessary to reduce crowd-out to acceptable levels. The state could, of course, contest this finding as unsupported by substantial evidence during administrative proceedings, as well as on judicial review. But the point it is that, in the abstract, the existing crowd-out regulation authorizes the agency to make such a finding and thereby to effectively require the state to impose particular procedures to prevent crowd-out.

The SHO Letter draws upon this existing authority by informing states of the particular crowd-out procedures it expects to require them to adopt in future reviews of their plans if they choose to extend coverage above 250% FPL – a change in policy based on accumulated nationwide experience and data showing that the states' current approaches to crowd-out have proven insufficiently effective. *See* Def.'s Br. at 5. Again, an individual state can contest this policy in the adjudicative process, by arguing that the state's preferred procedures will in fact provide reasonable protection against crowd-out, despite any variance from the SHO Letter. And CMS will have to defend its ultimate decision based on whether the states proposed procedures are "reasonable" as opposed to simply whether they conform to the SHO Letter. But nothing prevents the agency from forecasting in advance the decisions it expects to make on these matters. Its policy is ultimately rooted in existing legal authority and thus does not constitute a legislative rule. *See Mejia-Ruiz v. INS*, 51 F.3d 358, 364 (2d Cir. 1995) ("Unlike a legislative rule, § 3.4 does not have 'effect[s] *completely independent* of the statute.'") (quoting *United Technologies*

v. EPA, 821 F.2d 714, 718 (D.C. Cir. 1987) (quoting *Cabais v. Egger*, 690 F.2d 234, 238 n.9 (D.C. Cir. 1982) (emphasis in *Cabais*)) (internal quotation marks omitted)).

Plaintiffs rely heavily on language from the preamble to the existing regulations explaining that the regulations were intended to provide flexibility to the states in designing their own crowd-out procedures. Pls.' Br. at 39-40 (quoting 66 Fed. Reg. 2,602-04). The preamble also explains, though, that the regulations were designed to allow the "implementation of policies based on emerging research regarding substitution and on State experiences with substitution." 66 Fed. Reg. 2,602. At the time the regulations were promulgated, the significance of the crowd-out problem was unclear and the agency deemed it unwise to specify in advance what types of procedures would be needed to limit it. Instead, it chose simply to require the states to include "reasonable procedures" in their state plans – thereby allowing the states to experiment with different procedures, *but also* giving the agency a flexible standard by which it could decide the acceptability of specific procedures over time. The flexibility afforded by the regulation thus operates in two directions and was intended to leave a significant role for the agency. *See* 66 Fed. Reg. 2,602 ("We plan to work closely with each State to develop appropriate substitution strategies . . . ."). [18]

---

[18] Plaintiffs' also cite language from the preamble to the *proposed* implementing regulations, in which CMS stated that it was not proposing specific crowd-out procedures in the regulations in part because "the statute authorizes States to design approaches to prevent substitution, not the Federal government." 64 Fed. Reg. 60,922 (Nov. 8, 1999), *cited in* Pls.' Br. at 7. This language is overstated, however. While the statute envisions that states will propose crowd-out procedures in the first instance, the agency has statutory authority to specify what procedures it will approve. Indeed, in the same preamble, CMS proposed specific crowd-out procedures (*e.g.*, a minimum 6-month waiting period) for premium-assistance SCHIP programs, given the greater potential for crowd-out in this type of arrangement. 64 Fed. Reg. 60,922-23. Such procedures were included in the final regulations. *See* 42 C.F.R. § 457.810.

Since the issuance of the regulations, states extending coverage above 250% FPL have employed a variety of substitution procedures, as described in the SHO Letter. *See* SHO Letter at 1. And yet, in CMS's view, there is mounting evidence that substitution remains a serious and persistent problem in spite of these efforts. Accordingly, CMS is within its rights to decide that the crowd-out procedures employed by these states, regardless of whether they were deemed reasonable in the past, can no longer be considered reasonable now, and that more vigorous efforts to combat crowd-out are needed. *See* Smith Testimony, *supra*, at 5 (explaining that SHO Letter was issued because, "[i]n short, over time it became apparent that further action was necessary to remind states of their obligation for preventing 'crowd-out'"). The SHO Letter thus spells out specific higher benchmarks that the agency intends to use in assessing the reasonableness of states' crowd-out procedures going forward (with the understanding that the agency retains the discretion to approve alternative approaches on a case-by-case basis).

As explained in defendant's initial brief, this concededly marks a change from the agency's past *sub*-regulatory practice, but it does not require a change to the agency's existing regulations. *See* Def.'s Br. at 37-38. The regulations themselves leave open what crowd-out procedures qualify as "reasonable," and the agency is free to give meaning to that term through a general statement of policy or interpretive rule. *Central Texas Tel. Co-op, Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005) (stating that "an agency may use an interpretive rule to transform a vague statutory duty or right into a sharply delineated duty or right"); *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 667 (D.C. Cir. 1978) (finding no merit in the argument that "specific and detailed requirements cannot qualify as a 'general' statement of policy": "In the APA context, the term 'general' includes detailed requirements provided that they are of general as contrasted with particular applicability.").

In sum, it cannot be said that "in the absence of" the SHO Letter, "no legislative basis would exist for an enforcement action." *N.Y.C. Employees' Retirement Sys.*, 45 F.3d at 13 (internal quotation marks omitted). CMS already has authority under the SCHIP statute and regulations to require states to provide coverage in a way that reasonably prevents crowd-out, coordinates with other forms of insurance, and otherwise ensures the effective and efficient operation of this federally funded program. It also has the corresponding prerogative to tell the public how it intends to exercise this authority going forward – which is all the SHO Letter purports to do.[19]

CONCLUSION

For the foregoing reasons, as well as the reasons asserted in defendant's initial brief, plaintiffs' entire complaint should be dismissed for lack of jurisdiction. To the extent that the Court reaches plaintiffs' procedural challenge, it should be dismissed for failure to state a claim.

Respectfully submitted,

Dated: New York, New York
May 16, 2008

MICHAEL J. GARCIA
United States Attorney for the
Southern District of New York
Attorney for Defendant

By: */s/ Serrin Turner*
SERRIN TURNER
Assistant United States Attorney
86 Chambers Street, 3rd Floor
New York, New York 10007
Telephone: (212) 637-2701
Facsimile: (212) 637-2686
Email: serrin.turner@usdoj.gov

[19] Plaintiffs' claim that the SHO Letter violates 45 C.F.R. § 92.11(b), which states that a state plan need meet only federal requirements codified in statute or regulation, *see* Pls.' Br. at 33, fails for these same reasons. The SHO Letter merely advises states how CMS intends to enforce such existing requirements.